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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,203

04/09/2004

David Sidransky

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22907 7590 10/19/2005

BANNER & WITCOFF

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WASHINGTON, DC 20001

EXAMINER

JOYCE, CATHERINE

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/821,203	<b>Applicant(s)</b> SIDRANSKY ET AL.	
	<b>Examiner</b> Catherine M. Joyce	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Claims 1-24 are pending.

***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, 23, 24, as drawn to methods for distinguishing malignant from benign thyroid samples comprising determining the presence of a T to A transversion at nucleotide 1796 of BRAF, or as drawn to methods for detecting a mutation at nucleotide 1796 of BRAF, classified in class 435, subclass 4.
  - II. Claims 11-14, as drawn to methods for detecting a mutation at nucleotide 1796 of BRAF, classified in class 435, subclass 4.
  - III. Claims 15-16, as drawn to a method of treating a thyroid cancer patient comprising administering to the patient an inhibitor of BRAF serine/threonine kinase activity as disclosed in the specification, classified in class 514, subclass 1.
  - IV. Claims 15 and 17-19, as drawn to a method of treating a thyroid cancer patient comprising administering to the patient an inhibitor of BRAF serine/threonine kinase expression as disclosed in the specification, classified in class 514, subclass 1.
  - V. Claims 20-22, as drawn to a method of treating a thyroid cancer patient comprising administering to the patient an inhibitor of the Ras-Raf-MAPK pathway, classified in class 514, subclass 1.

- VI. Claims 20-22, as drawn to a method of treating a thyroid cancer patient comprising administering to the patient an inhibitor of the Raf/MEK/ERK signaling pathway, classified in class 514, subclass 1.

Claims 21 and 22 will be examined as they are drawn to the elected invention.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions of groups I through VI are materially distinct methods that differ at least in objectives, method steps and reagents. For example, Group I is drawn to methods for distinguishing malignant from benign thyroid samples, Group II is drawn to methods for detecting a mutation at nucleotide 1796 of BRAF, Group III is drawn to drawn to methods of treating a thyroid cancer patient comprising administering to the patient an inhibitor of BRAF serine/threonine kinase activity, Group IV is drawn to drawn to methods of treating a thyroid cancer patient comprising administering to the patient an inhibitor of BRAF serine/threonine kinase expression, Group V is drawn to drawn to a method of treating a thyroid cancer patient comprising administering to the patient an inhibitor of the Ras-Raf-MAPK pathway, and Group VI is drawn to drawn to a method of treating a thyroid cancer patient comprising administering to the patient an inhibitor of the Raf/MEK/ERK signaling pathway. Furthermore, each of the groups employs chemically distinct reagents to accomplish the differing objectives. Searching all of the groups together would pose an undue search burden.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising methods for distinguishing malignant from benign thyroid samples. The

species are as follows: (a) providing a diagnosis based on the presence or absence of a transversion (claim 5); (b) providing a prognosis based on the presence or absence of a transversion (claims 6, 23 and 24); (c) determining a therapeutic regimen for the human using as a factor the presence or absence of the transversion (claim 7). The methods are patentably distinct because they are directed to highly divergent endpoints.

6. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

7. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

Art Unit: 1642

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


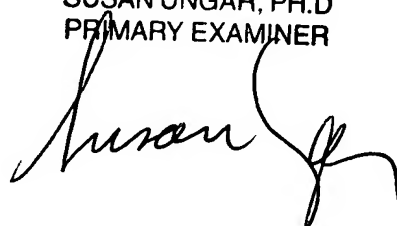
10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D  
PRIMARY EXAMINER



Catherine M. Joyce  
Examiner  
Art Unit 1642